This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: Friday, March 16, 2001

510(k) number: K010815

Applicant Information:

NTERO, Inc.
1137D San Antonio Rd
Palo Alto, CA 94303

Contact Person: D. Bommi Bommannan PhD., J.D.
Phone Number: (650) 428-1000 ext. 101
Fax Number: (650) 428-0700

Device Information:

Classification: Class II
Trade Name: NTERO NOMAD™ System
Classification Name: Electrosurgical Device and accessories (21 CFR 884.4120)

Equivalent Device:

The subject device is substantially equivalent in intended use and/or method of operation to the Everest Evershears Bipolar Scissors (K000496), the Starion Instruments Power Point Cautery Grasper (K002547), and the Karl Storz Laparoscopic Thermocoagulator (K955756 and K963852).

Intended Use:

NTERO's NOMAD™ System is intended to coagulate and cut tissue during the performance of open surgical procedures.

Test Results:

Performance

Results of animal testing demonstrate that NTERO's NOMAD™ System is safe and effective for its intended function.

Biocompatibility

The materials used in NTERO's Applicator have been shown to be biocompatible when tested in accordance with ISO 10993-1 requirements.

Summary:

Based on the intended use, product, performance and biocompatibility information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 5 2001

D. Bommi Bommannan, Ph.D., J.D.
President and CEO
NTERO, Inc.
1137D San Antonio Road
Palo Alto, California 94303

Re: K010815
Trade/Device Name: NTERO NOMAD™ System
Regulation Number: 878.4400
Regulatory Class: II
Product Code: GEI
Dated: March 16, 2001
Received: March 19, 2001

Dear Dr. Bommannan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K010815

Device Name: NTERO NOMAD™ System

Indications for Use:

The NTERO NOMAD™ System is intended to coagulate and cut tissue during the performance of open surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010815

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)